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FEB 6 2013

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

2441 Michelle Drive, Tustin, CA 92780 Phone: (714) 730-5000

510(k) SUMMARY

1. SUBMITTER'S NAME:

Toshiba America Medical Systems, Inc.

2. ADDRESS:

2441 Michelle Drive Tustin, CA. 92780-2068

3. ESTABLISHMENT REGISTRATION:

2020563

4. CONTACT PERSON:

Charlemagne Chua Manager, Regulatory Affairs (714) 669-7896

5. Date Prepared:

December 21, 2012

6. TRADE NAME(S):

Diagnostic Ultrasound System Aplio 500 Model TUS-A500 V3.0 Aplio 400 Model TUS-A400 V3.0 Aplio 300 Model TUS-A300 V3.0

7. COMMON NAME:

System, Diagnostic Ultrasound

8. DEVICE CLASSIFICATION:

Class II

Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [per 21 CFR 892.1550] Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [per 21 CFR 892.1560] Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [per 21 CFR 892.1570]

9. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Aplio 500/400/300 Diagnostic Ultrasound System	Toshiba America Medical Systems	K121422	. August 16, 2012

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 and Aplio 300 Model TUS-A300 are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex linear array, and sector array with frequency ranges between approximately 2 MHz to 12 MHz.

12. SUMMARY OF INTENDED USES:

The Diagnostic Ultrasound System Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 And Aplio 300 Model TUS-A300 is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intraoperative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, and musculo-skeletal (both conventional and superficial).

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio 500/400/300 Diagnostic Ultrasound System, K121422, marketed by Toshiba America Medical Systems. The **Aplio 500 Model TUS-A500 Version 3.0**, **Aplio 400 Model TUS-A400 Version 3.0** and **Aplio 300 Model TUS-A300 Version 3.0**, functions in a manner similar to and is intended for the same use as the predicate device. The subject device includes modifications to the cleared device which improves upon existing features such as imaging and report/communication transfer. Additionally, two new transducers, a new 4D optional feature, Luminance, and new hardware items intended to improve ease of use, are now available with the subject device.

A comparison table is included in this submission detailing the similarities and differences between the predicate device and the subject device.

14. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, IEC 62304, NEMA UD3 Output Display and ISO 10993-1 standards.

15. TESTING

Risk Analysis, Verification/Validation testing conducted through bench testing which are included in this submission demonstrates that the requirements for the improved/added features have been met.

Software Documentation for a Moderate Level of Concern, per the FDA guidance

document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices.

16. CONCLUSION

The modifications incorporated into the Aplio 500 Model TUS-A500 Version 3.0, Aplio 400 Model TUS-A400 Version 3.0 and Aplio 300 Model TUS-A300 Version 3.0 do not change the indications for use or the intended use of the device. Based upon bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-002

February 6, 2013

Toshiba America Medical Systems, Inc. c/o Mr. Charlemagne Chua Manager, Regulatory Affairs 2441 Michelle Drive TUSTIN CA 92780-2068

Re: K123992

Trade/Device Name: AplioTM 500/400/300 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: December 21, 2012 Received: December 26, 2012

Dear Mr. Chua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the AplioTM 500/400/300 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

PST-25BT	<u>PVT-661VT</u>	PVT-745BTV	PLT-1005BT
PST-30BT	<u>PVT-781VT</u>	PVT-770RT	PLT-1202S
PST-50BT	<u>PVT-674BT</u>	PLT-604AT	PLT-1204BT
PST-65AT	<u>PVT-675MV</u>	PLT-704AT	PLT-1204BX
<u>PVT-375BT</u>	<u>PVT-681MV</u>	PLT-704SBT	PLT-1204MV
<u>PVT-375MV</u>	<u>PVT-712BT</u>	PLT-705BTF	<u>PET-508MA</u>
PVT-382BT	<u>PVT-745BTF</u>	<u>PVT-705BTH</u>	<u>PET-510MB</u>
PVT-382MV	PVT-745BTH_	<u>PLT-805AT</u>	<u>PET-512MC</u>

PC-20M

PC-50M

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Sean M. Boyd -S

for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

	
Aplio 500/400/30	0 V3.0 Diagnostic Ultrasound System
US-A300 is indicate human body using the following clinical tric, small organs, triliac (both adult and	odel TUS-A500, Aplio 400 Model TUS- ed for the visualization of structures, and ultrasound and to provide image applications: fetal, abdominal, intra- ans-vaginal, trans-rectal, neonatal pediatric), peripheral vascular, nventional and superficial).
AND/OR	Over-The-Counter Use(21 CFR 807 Subpart C)
LOW THIS LINE-CON	ITINUE ON ANOTHER PAGE IF NEEDED)
	nostics and Radiological Health (OIR)
ean M.Bc	yd -S
	Page 1 of <u>1</u>
gn Off) Ogical Health and Radiological Health	
	ystem Aplio 500 Mo US-A300 is indicate human body using using the following clinical tric, small organs, triliac (both adult and illo-skeletal (both confice of In Vitro Diagram AND/OR AND/OR

System:	Aplio 500, Aplio 400, Aplio 300) V3.0
Transduc		

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operatio	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	P	P	P	P	P	2	P	P	P		P	5,7,8, 9,10,14
Abdominal	P	P	P	P	P	- 2,3	P	P	P		P	5,7,8, 9,10,11,12,14
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			4,5,7,11
Intra-operative (Neuro)												·
Laparoscopic												
Pediatric	P	P	P	P	P	2,3	P	P	P		P	5,7,8,9,10,12,14
Small Organ (Note 1)	P	P	P		P	2	P	P	P			4.5,6,7,8,9,10,11,14
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
Trans-rectal	P	Р	P		P	2	P	P	P		P	4,5,7,11,12
Trans-vaginal	P	P	P		P	2	P	P	Р		P	4,5,7,11,12
Trans-urethral	Ī											
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	Р	P		Р	2	P	P	P			4,5,6,7,8,9,10,11,14
Musculo-skeletal (Superficial)	Р	P	P		P	2	P	P	P			4,5,6,7,8,9,10,11,14
Intravascular												
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)	Π		T									
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P	P	P	2	P	P	P			4,5,6,7,8,9,10,11,14
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers: K121422 and K103629

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

(Division Sign Off)

Sean M. Boyd -S

Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operation	on				· · · · · · · · · · · · · · · · · · ·				
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	İΤ											
Fetal	1											
Abdominal	P	P	P	P	P	3	P	Р	P			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)			T									
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
Trans-rectal										1		
Trans-vaginal												
Trans-urethral										٠,		
Trans-esoph. (non-Card.)	Ī		1				Ī			1		
Musculo-skeletal (Conventional)							[Т		
Musculo-skeletal (Superficial)												
Intravascular								T		T		
Other (Specify)												
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)												
Intra-cardiac	T		T	Γ								
Other (Specify)	Τ		T									
Peripheral vessel	T		T							1		
Other (Specify)			T	Π	1					T		

N = new indication; P = previously cleared by FDA; E = added under this appendixPrevious 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operation	on		· <u>'</u>		·····				
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal	Ì			Ţ								
Abdominal	P	P	P	P	P	3	P	P	P			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic	İ								-			
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)	Π		ſ									
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	·P	P	P	P	P	3	P	P	P			
Trans-rectal	Ť			Ī	Ì							
Trans-vaginal			T									
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)				İ								
Musculo-skeletal (Superficial)												
Intravascular			Ī									
Other (Specify)	\Box											
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)			1	1								
Trans-esoph. (Cardiac)			1					1 .				
Intra-cardiac	T											
Other (Specify)	T	1	T									
Peripheral vessel	Τ		T					1				
Other (Specify)	П		1					1				

N= new indication; P= previously cleared by FDA; E= added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Sean M. Boyd -S

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

110(k) 125992

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	3	P	P	P			11
Intra-operative (Abdominal)												
Intra-operative (Neuro)			1									
Laparoscopic .	Ī										-	
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)												
Neonatal Cephalic	P	P	P	P	P	3	P	P	P			
Adult Cephalic	P	.P	P	P	P	3	P	P	P			
Trans-rectal												
Trans-vaginal	Ì		T									
Trans-urethral			1									
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)										1		
Intravascular		1										
Other (Specify)	T											
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4.13
Intravascular (Cardiac)					T							
Trans-esoph. (Cardiac)	T			Ţ								
Intra-cardiac												
Other (Specify)		1										
Peripheral vessel	Т	T										
Other (Specify)												

N= new indication; P= previously cleared by FDA; E= added under this appendix Previous 510(k) of the transducer: K121422

Note 1	Small organ	includes	thyroid,	breast	and	testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT Note 14 Boost

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Division of Radiological Health

Office of In Vitro Diagnostics and Ra **∵ern•M**. Boyd -S

Transducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on		 		·······				
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	† –		┪									
Fetal	1											
Abdominal	P	P	P	P	P	3	P	P	P	-		11
Intra-operative (Abdominal)												
Intra-operative (Neuro)	1											
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)		Ì	Ì					Ì				
Neonatal Cephalic	P	P	P	P	P	3	P	Р	P			
Adult Cephalic .	P	P	P	P	P	3	Р	P	P			
Trans-rectal	T		Ť							Ì		
Trans-vaginal												
Trans-urethral												1
Trans-esoph. (non-Card.)	T							1				
Musculo-skeletal (Conventional)		İ						İ				
Musculo-skeletal (Superficial)												
Intravascular	1			T								
Other (Specify)				1								1
Cardiac Adult	P	P	P	P	P	3	P	P	P	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)	1	Π	T									
Trans-esoph. (Cardiac)		Π	T									
Intra-cardiac	T.	T	T	1								
Other (Specify)										Ι		
Peripheral vessel	T		T									
Other (Specify)	T	T		T								

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note	l	Small	organ	inclu	les t	hyroid,	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT Note 14 Boost (Division Sign Offic

Division of Radiological Hoose

Orfice of In Vitro Diagnostics and Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

510(k)

I. BOY

Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify) *	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic													
Fetal	P	P	P		P	2	P	P	P			5, 7	
Abdominal	P	P	P		P	2	P	P	P			5, 7,11,12	
Intra-operative (Abdominal)	T												
Intra-operative (Neuro)													
Laparoscopic	T		Τ										
Pediatric	P	P	P		P	2	P	P	P			5, 7,12	
Small Organ (Specify) (1)													
Neonatal Cephalic												Τ	
Adult Cephalic													
Trans-rectal													
Trans-vaginal	T												
Trans-urethral	T				· .								
Trans-esoph. (non-Card.)	T												
Musculo-skeletal (Conventional)	T												
Musculo-skeletal (Superficial)	T]			
Intravascular	Т											T	
Other (Specify)	Т												
Cardiac Adult	Т									1			
Cardiac Pediatric													
Intravascular (Cardiac)	T												
Trans-esoph. (Cardiac)	Τ												
Intra-cardiac	T												
Other (Specify)	T		T				T			T			
Peripheral vessel	T		T	T									
Other (Specify)	T												

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Transducer: PVT-375MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	t											
Fetal	P	P	P		P	2	P	P	P	<u> </u>	N	5,7,8,9,10
Abdominal	P	P	P		P	2	P	P	P		N	5,7,8,9,10
Intra-operative (Abdominal)												<u> </u>
Intra-operative (Neuro)												
Laparoscopic	T											
Pediatric	P	P	P		P	2	P	P	P		N,	5,7,8,9,10
Small Organ (Specify) (1)								1				
Neonatal Cephalic												
Adult Cephalic								T .				
Trans-rectal												
Trans-vaginal				T				T				
Trans-urethral			T					Ţ				
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)			-									
Intravascular												
Other (Specify)	T							Γ.				
Cardiac Adult						1.						
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)			I									
Intra-cardiac												
Other (Specify)												
Peripheral vessel				Ĭ			T					
Other (Specify)	T											

 $N=\mbox{new indication; }P=\mbox{previously cleared by FDA; }E=\mbox{added under this appendix Previous }510(k)$ of the transducer; K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K/2399.7

Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	 	<u> </u>	 	-									
Fetal	P	P	P		P	2	P	P	P			5, 7	
Abdominal	P	P	P		P	2	P	P	P			5, 7,12	
Intra-operative (Abdominal)													
Intra-operative (Neuro)	Π												
Laparoscopic													
Pediatric	P	P	P		P	2	P	P	P			5, 7,12	
Small Organ (Specify) (1)													
Neonatal Cephalic			1							T :			
Adult Cephalic								·					
Trans-rectal							[
Trans-vaginal													
Trans-urethral													
Trans-esoph. (non-Card.)	Π												
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)			T			1							
Intravascular								T					
Other (Specify)												}	
Cardiac Adult			Ţ										
Cardiac Pediatric													
Intravascular (Cardiac)													
Trans-esoph. (Cardiac)													
Intra-cardiac													
Other (Specify)													
Peripheral vessel													
Other (Specify)	T												

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Separan M. Boyd -S

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510KL 16/23/92

Transducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of (Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic			1	 							/	
Fetal	P	P	· P		P	2	P	P	P		P	5,7,9
Abdominal	P	P	P		P	2	P	P	P		P	5,7,9
Intra-operative (Abdominal)												
Intra-operative (Neuro)			1									
Laparoscopic												
Pediatric	P	P	P		P	2	P	P	P		P	5,7,9
Small Organ (Specify) (1)						İ		Ì				
Neonatal Cephalic	-	İ										
Adult Cephalic												
Trans-rectal	Ì	Г	1		ĺ							
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)			T	1								
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular	T											
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	T		T			-						
Intra-cardiac		T	1	П	1	-				1		
Other (Specify)			T	T			[]			
Peripheral vessel	Γ		T							T		
Other (Specify)				1	1			1		T		

N = new indication; P = previously cleared by FDA; E = added under this appendixPrevious 510(k) of the transducer: K121422

Moto 1	Small organ	includes	thuroid	broact a	ad tosticle
Note 1	Small organ	includes	invroid.	preast a	na testicie.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign OffSean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k)

Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В		PWD		Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	-											 	
Fetal												T	
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric													
Small Organ (Specify) (1)			Ì										
Neonatal Cephalic			İ	İ							•		
Adult Cephalic										ĺ			
Trans-rectal	P	P	P	ĺ	P	2	Р	P	P			4,5,7,11	
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,7,11	
Trans-urethral				1									
Trans-esoph. (non-Card.)	1									Ì		<u> </u>	
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)													
Intravascular										1			
Other (Specify)													
Cardiac Adult								Ì					
Cardiac Pediatric	T												
Intravascular (Cardiac)												-	
Trans-esoph. (Cardiac)	T			T			T	1			<u> </u>		
Intra-cardiac]			T		1		Ì	
Other (Specify)						-[T					
Peripheral vessel		Г								T			
Other (Specify)										T			

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

L123992

Transducer: PVT-781VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on				···········				
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	T	<u> </u>										
Fetal	T								-			
Abdominal	T											
Intra-operative (Abdominal)												
Intra-operative (Neuro)	T		Ì									
Laparoscopic	T											
Pediatric	Ì								_			
Small Organ (Specify) (1)	T						Ì			Ī		
Neonatal Cephalic	1							ŀ				
Adult Cephalic												
Trans-rectal	E	E	E		E	2	Ē	E	Е			4,5,7,11,12
Trans-vaginal	E	E	E	ļ	E	2	E	E	Е			4,5,7,11,12
Trans-urethral	Ť	İ	T									
Trans-esoph. (non-Card.)	T		1									
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	Ī											
Intravascular	T	T										
Other (Specify)	1	1										
Cardiac Adult	1											
Cardiac Pediatric	T		1	Ì								
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)			T									
Intra-cardiac	T	Γ		T			T			T	Π	
Other (Specify)	1	T	T									
Peripheral vessel	1									1		
Other (Specify)	T	Ì	1	1								

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: N/A (This transducer is being added under this submission)

Note 1	Small	organ	includes	thyroid,	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K/23992

Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic			<u>† </u>										
Fetal	P	P	P	Ĭ	P	2	P	P	P			5,7,14	
Abdominal	P	P	P		P	2	P	P	P			5,7,14	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic		Π	1										
Pediatric	P	P	P		P	2	P	P	P			5,7,14	
Small Organ (Specify) (1)			1										
Neonatal Cephalic													
Adult Cephalic													
Trans-rectal													
Trans-vaginal		1								<u> </u>			
Trans-urethral			T										
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)								-					
Musculo-skeletal (Superficial)													
Intravascular												T	
Other (Specify)		Γ	T										
Cardiac Adult			T										
Cardiac Pediatric													
Intravascular (Cardiac)													
Trans-esoph. (Cardiac)													
Intra-cardiac													
Other (Specify)													
Peripheral vessel													
Other (Specify)		T	T										

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT -

Note 14 Boost

Sean M. Boyd -S

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Transducer: PVT-675MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	†		<u> </u>										
Fetal	P	P	P		P	2	P	P	P		P	5,7,8,9,10	
Abdominal	P	P	P		P	2	P	P	P		Р	5,7,8,9,10	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P		P	2	P	P	P		P	5,7,8,9,10	
Small Organ (Specify) (1)	1												
Neonatal Cephalic								·					
Adult Cephalic													
Trans-rectal				Ì									
Trans-vaginal				T									
Trans-urethral			 	1									
Trans-esoph. (non-Card.)			T					T					
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)]				
Intravascular													
Other (Specify)													
Cardiac Adult	T												
Cardiac Pediatric	Т			T					T				
Intravascular (Cardiac)													
Trans-esoph. (Cardiac)													
Intra-cardiac	1]	L						
Other (Specify)													
Peripheral vessel	1				•								
Other (Specify)	T										Ī		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Nioto 1	Small organ	includes threeid	breast and testicle

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Office of in Vitro Diagnostics and Radiological Health

510(k) K123992

Transducer: PVT-681MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	T	_	1					<u> </u>				
Fetal			Ī									-
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)										·		
Laparoscopic				Ì								
Pediatric	1										İ	
Small Organ (Specify) (1)	Ī		1	İ								
Neonatal Cephalic											<u> </u>	
Adult Cephalic	İ							İ				
Trans-rectal	P	P	P	i	P	2	P	P	P		P	4,5,7,9,11
Trans-vaginal	P	P	P		P	2	P	P	P		P	4,5,7,9,11
Trans-urethral												
Trans-esoph. (non-Card.)	1			1						1		İ
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	1											Ì
Intravascular												
Other (Specify)												
Cardiac Adult	\top											
Cardiac Pediatric	1	Ī								İ		
Intravascular (Cardiac)	T				Ī	-						
Trans-esoph. (Cardiac)	T						i					
Intra-cardiac	1		1			-		1			Γ	<u>"</u>
Other (Specify)	1		T							T		
Peripheral vessel			T									1
Other (Specify)			Ī		<u> </u>					1	i	İ

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K121422

Ninta	1 Cmall	organ	includes	thursd	becaset	and testicle

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health Boyd - S
Office of In Vitro Diagnostics and Radiological Health

510111 1(123967

Transducer: PVT-712BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	\dagger										-		
Fetal								· .	-				
Abdominal	P	P	P		P	2	P	P	P		P	5,7	
Intra-operative (Abdominal)													
Intra-operative (Neuro)													
Laparoscopic													
Pediatric	P	P	P		P	2	P	P	P			5,7	
Small Organ (Specify) (1)													
Neonatal Cephalic	P	P	P		P	2	P	P	P			5,7	
Adult Cephalic													
Trans-rectal	T											1	
Trans-vaginal													
Trans-urethral								İ					
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)		Ì											
Intravascular		Ì											
Other (Specify)													
Cardiac Adult	Ti-		T										
Cardiac Pediatric	Ť	Π	1										
Intravascular (Cardiac)	Ī			T T									
Trans-esoph. (Cardiac)				T									
Intra-cardiac	Τ_			Г									
Other (Specify)	1	Π											
Peripheral vessel	1	Ť		<u> </u>		1		T			<u> </u>		
Other (Specify)	<u> </u>	1	T										

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiolog M. Boyd -S Prescription Use Only (Per 21 CFR 801.109)

Transducer: PVT-745BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	1	<u> </u>	1										
Fetal													
Abdominal	P	P	P		P	2	P	P	P			5,7	
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7	
Intra-operative (Neuro)		Ī				1							
Laparoscopic													
Pediatric	1	Ì	Ī										
Small Organ (Specify) (1)		İ	T	İ									
Neonatal Cephalic		İ	İ	İ									
Adult Cephalic		T	İ										
Trans-rectal		İ	T	1									
Trans-vaginal	1												
Trans-urethral	T	Т											
Trans-esoph. (non-Card.)	T	Π										<u> </u>	
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)		Ì	T										
Intravascular		Т											
Other (Specify)		Ī											
Cardiac Adult													
Cardiac Pediatric		Ť											
Intravascular (Cardiac)			T	T									
Trans-esoph. (Cardiac)	1	Τ	T	Τ									
Intra-cardiac	1	T	T										
Other (Specify)		Π											
Peripheral vessel	1	Τ		T									
Other (Specify)		T	T										

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

51010 K/23992 Sean M. Boyd -S

Transducer: PVT-745BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	 	<u> </u>	1									<u> </u>	
Fetal													
Abdominal	P	Р	P	<u> </u>	P	2	P	P	P			5,7	
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7	
Intra-operative (Neuro)												Γ.	
Laparoscopic													
Pediatric	-j	İ		<u> </u>		<u> </u>			<u> </u>	Ì		Ì	
Small Organ (Specify) (1)	1	İ	1							İ		İ	
Neonatal Cephalic	1		Ì	<u> </u>						Ì			
Adult Cephalic			ĺ								İ		
Trans-rectal		ĺ	Ť					Ì		1	<u> </u>		
Trans-vaginal	1									1	i		
Trans-urethral	T									İ			
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)								İ		Ì			
Intravascular					-	1		<u> </u>				<u> </u>	
Other (Specify)	İ	Ī		<u> </u>							Ì	1	
Cardiac Adult	Ť	İ	İ					İ					
Cardiac Pediatric	1		 			İ.				Ì	İ		
Intravascular (Cardiac)	T	Ì	İ	İ									
Trans-esoph. (Cardiac)	İ				1			İ		ļ		····	
Intra-cardiac			T							T			
Other (Specify)						Ï						İ -	
Peripheral vessel	i	T	1					1		1	<u> </u>		
Other (Specify)		Ì		1	İ		Ī	Ť –		T	i	1	

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Transducer: PVT-745BTV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	 	-										
Fetal	1											
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric			T									1
Small Organ (Specify) (1)	<u> </u>	<u> </u>										
Neonatal Cephalic		ĺΤ										
Adult Cephalic			T									
Trans-rectal						Ì	Ì	Ì		<u> </u>		
Trans-vaginal			Ì				· ·				·	
Trans-urethral			<u> </u>	<u> </u>		· ·						
Trans-esoph. (non-Card.)	Ť										i	
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	1					1						
Intravascular	İ											
Other (Specify)	1	·	1									
Cardiac Adult			T									
Cardiac Pediatric			Ì				i					,
Intravascular (Cardiac)					<u> </u>		T				Ì	
Trans-esoph. (Cardiac)				1	1							
Intra-cardiac	T				<u> </u>							
Other (Specify)	1	1		ļ								
Peripheral vessel	†		1	İ		T						
Other (Specify)		İ	 			İ						

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1	Small	organ	includes	thyroid,	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

(Division Sign Off) Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

Sean M. Boyd -S

Transducer: PVT-770RT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation													
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]		
Ophthalmic	ļ		1			<u> </u>								
Fetal														
Abdominal														
Intra-operative (Abdominal)														
Intra-operative (Neuro)														
Laparoscopic	Ī								·					
Pediatric												T		
Small Organ (Specify) (1)			Ì											
Neonatal Cephalic	Ì		İ											
Adult Cephalic														
Trans-rectal	P	P	P		P	2	P	P	P			4,5,7,11		
Trans-vaginal	P	P	P		P	2	P	P	P			4,5,7,11		
Trans-urethral				· ·										
Trans-esoph. (non-Card.)														
Musculo-skeletal (Conventional)			1											
Musculo-skeletal (Superficial)	T		T											
Intravascular		Ī	T											
Other (Specify)	Ì		ĺ	İ										
Cardiac Adult	Ì	 	T											
Cardiac Pediatric	Π			Ĭ .										
Intravascular (Cardiac)				T										
Trans-esoph. (Cardiac)	T		T	1			T				Γ			
Intra-cardiac	T				İ —									
Other (Specify)	T	Π	T											
Peripheral vessel							T							
Other (Specify)	T	1		1								T		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

No	ote	1	Small	organ	includ	les t	hyroid,	, breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT Note 14 Boost (Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

510(k) 1423942

Sean M. Boyd -S

Transducer: PLT-604AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	 		 			7				1			
Fetal													
Abdominal													
Intra-operative (Abdominal)												T	
Intra-operative (Neuro)													
Laparoscopic													
Pediatric													
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7	
Neonatal Cephalic			Ì										
Adult Cephalic	1												
Trans-rectal													
Trans-vaginal			1										
Trans-urethral	1												
Trans-esoph. (non-Card.)													
Musculo-skeletal (Conventional)	P	Р	P		P	2	P	Р ·	P			5,7	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7	
Intravascular			T										
Other (Specify)													
Cardiac Adult	1	Ī			<u> </u>								
Cardiac Pediatric	T							T					
Intravascular (Cardiac)										}		[
Trans-esoph. (Cardiac)													
Intra-cardiac												AARIO GEORGIA	
Other (Specify)			T								Γ		
Peripheral vessel	P	P	P		P	2	P	P	P	T	İ	5,7	
Other (Specify)			1.								İ		

 $N=\mbox{new}$ indication; $P=\mbox{previously}$ cleared by FDA; $E=\mbox{added}$ under this appendix Previous 510(k) of the transducer; K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123992 Sean M. Boyd -S

Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	+					İ							
Fetal													
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)	T		T										
Laparoscopic			1										
Pediatric	T												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7	
Neonatal Cephalic			İ						·				
Adult Cephalic	1												
Trans-rectal		İ		Ì									
Trans-vaginal		<u> </u>	1										
Trans-urethral			ĺ										
Trans-esoph. (non-Card.)		П								T			
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P			5,7	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7	
Intravascular	1												
Other (Specify)								T					
Cardiac Adult	T												
Cardiac Pediatric			T				-						
Intravascular (Cardiac)			1										
Trans-esoph. (Cardiac)		Γ		1									
Intra-cardiac	1	T	T										
Other (Specify)			T										
Peripheral vessel	P	P	P		P	2	P	P	P			5,7	
Other (Specify)		Г	T				T						

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle. Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

Office of In Vitro Diagnostics and Radiological HealtM. Boyd -S

Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation												
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	1	 											
Fetal													
Abdominal													
Intra-operative (Abdominal)													
Intra-operative (Neuro)												<u> </u>	
Laparoscopic		T											
Pediatric													
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7,14	
Neonatal Cephalic													
Adult Cephalic													
Trans-rectal		Γ											
Trans-vaginal													
Trans-urethral													
Trans-esoph. (non-Card.)]	
Musculo-skeletal (Conventional)	P	P	P		Р	2	P	P	P			5,7,14	
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7,14	
Intravascular	T			Γ.								I	
Other (Specify)]	
Cardiac Adult												1	
Cardiac Pediatric													
Intravascular (Cardiac)]	
Trans-esoph. (Cardiac)													
Intra-cardiac													
Other (Specify)													
Peripheral vessel	P	P	P		P	2	P	P	P			5,7,14	
Other (Specify)			T	T				I					

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Office of In Vitro Diagnostics and Parish Mea Boyd -S

Transducer: PLT-705BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic ·	\dagger	┢╴	 									
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	2	P	P	P			5,7
Intra-operative (Neuro)	1											
Laparoscopic	1-											
Pediatric			1	Ì		İ						
Small Organ (Specify) (1)	T		ĺ	T								
Neonatal Cephalic			1									
Adult Cephalic			Ť		·							
Trans-rectal .	1		T) · · · · · · · · · · · · · · · · · · ·								
Trans-vaginal	1		Ì									
Trans-urethral	T											
Trans-esoph. (non-Card.)	1	П	T									
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular	1	Г										
Other (Specify)												
Cardiac Adult			ĺ		<u> </u>					Ī	<u> </u>	
Cardiac Pediatric	T		T	İ						Ì	Ì	
Intravascular (Cardiac)	Т											
Trans-esoph. (Cardiac)												
Intra-cardiac										1		
Other (Specify)												
Peripheral vessel		Π										
Other (Specify)	\top											

N= new indication; P= previously cleared by FDA; E= added under this appendix Previous 510(k) of the transducer: K121422

	Note 1	Small organ	includes thyroid	, breast	and testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

51000 H 2 3992 Sean M. Boyd -S

Transducer: PVT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D .	Other [Note]
Ophthalmic	<u> </u>		 							<u> </u>		
Fetal												
Abdominal	P	P	P		P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	P	P		P	. 2	P	P	P			5,7
Intra-operative (Neuro)		İ										
Laparoscopic		İ	ĺ									
Pediatric				Ì							Ī	Ì
Small Organ (Specify) (1)	İ											
Neonatal Cephalic	Ť	İ	Ì	Ì				Ì		Ì	İ	Ì
Adult Cephalic		İ										
Trans-rectal			İ									
Trans-vaginal			İ							ĺ	İ	
Trans-urethral	1		1.					İ				
Trans-esoph. (non-Card.)		Ì										
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)	T	 	T					Ì		Ì		
Cardiac Adult	T-		T									
Cardiac Pediatric	1		1									
Intravascular (Cardiac)	1	1	1								Γ	
Trans-esoph. (Cardiac)	1	Γ	1							ĺ		Ī
Intra-cardiac			1		<u> </u>			1				
Other (Specify)	1											
Peripheral vessel					Ī		<u> </u>				<u> </u>	
Other (Specify)								Ì				T

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color Note 11 Elastography Note 12 Fusion

Note 13 2D WMT Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) 123492

Sean M. Boyd -S

Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic ,	 		 									
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)	1		T									
Laparoscopic												
Pediatric	<u> </u>											
Small Organ (Specify) (1)	P	P	P	<u> </u>	P	2	P	P	P			5,6,7,11
Neonatal Cephalic			Ť –									
Adult Cephalic	İ		Ī									
Trans-rectal	T		İ	ĺ	Ì							
Trans-vaginal			T									
Trans-urethral	1											
Trans-esoph. (non-Card.)	1	Π	Ť	· ·	Ĭ		l					
Musculo-skeletal (Conventional)	Р	P	P		P	2	P	P	P			5,6,7,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,6,7,11
Intravascular		Ì	1							1		
Other (Specify)			j		Ì							
Cardiac Adult	T		1									
Cardiac Pediatric							T					
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)			1									
Intra-cardiac	T		T									
Other (Specify)			T								Ī	
Peripheral vessel	P	P	P		P	2	P	P	P	\Box		5,6,7,11
Other (Specify)			T		1	T						

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note	1	Small	organ	includes	thyroid,	breast	and	testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

23992 Sean M. Boyd -S

Transducer: PLT-1005BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operatio	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	<u> </u>	-										
Fetal												
Abdominal	1											
Intra-operative (Abdominal)												
Intra-operative (Neuro)		Ť										
Laparoscopic												
Pediatric	ĺ									[
Small Organ (Specify) (1)	E	E	E		E	2	Е	Е	E			5,6,7,11,14
Neonatal Cephalic	Π											
Adult Cephalic												
Trans-rectal		Π										
Trans-vaginal	T											
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	Е	Е	E		E	2	E	Е	E			5,6,7,11,14
Musculo-skeletal (Superficial)	E	E	E		E	2	E	E	Е			5,6,7,11,14
Intravascular												,
Other (Specify)]					
Cardiac Adult			T					T				
Cardiac Pediatric												
Intravascular (Cardiac)	T											
Trans-esoph. (Cardiac)	1		Ţ									
Intra-cardiac												
Other (Specify)												
Peripheral vessel	E	E	Ė		E	2	Е	E	E			5,6,7,11,14
Other (Specify)		Γ					<u> </u>				T	

N = new indication; P = previously cleared by FDA; E = added under this appendixPrevious 510(k) of the transducer: N/A (This transducer is being added under this submission)

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

Office of In Vitro Diagnostics and Radiological Health Sean IVI. Boyd -S

510(K) K/2 3992

Transducer: PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	B	М	PWD	CWD	Color Doppler	Combined (Specify)	THE	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic			1									
Fetal	Ì		Ť									
Abdominal												
Intra-operative (Abdominal)	P	P	P		P	2	P		P			4,5,11
Intra-operative (Neuro)			T					-		1		Ì
Laparoscopic										 		
Pediatric							<u></u>					Ì
Small Organ (Specify) (1)	P	P	P		P	2	P		P	Ī		4,5,11
Neonatal Cephalic								Ì		İ		Ì
Adult Cephalic								Ì		İ		İ
Trans-rectal	Ť	· · · ·	1					Ì		i .		İ
Trans-vaginal								Ì				
Trans-urethral				İ								
Trans-esoph. (non-Card.)			T					1		1		
Musculo-skeletal (Conventional)	P	P	P		P	2	Р		P		Ì	4,5,11
Musculo-skeletal (Superficial)	P	P	P		P	2	P		P		Ì	4,5,11
Intravascular		П						1			i	
Other (Specify)					j							
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	Π					1						
Intra-cardiac			T							Ţ		
Other (Specify)			T	1								
Peripheral vessel	N	N	N		N	2	N	1	N			4,5,11
Other (Specify)								1				

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K121422

Note 1, Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	1			<u> </u>								
Fetal												
Abdominal									·			
Intra-operative (Abdominal)	-											
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			4,5,6,7,11
Neonatal Cephalic	ĺ											
Adult Cephalic												
Trans-rectal	T		Ī									
Trans-vaginal	1 .											
Trans-urethral												
Trans-esoph. (non-Card.)											· ·	
Musculo-skeletal (Conventional)	P	P	Р		P	. 2	P	P	P			4,5,6,7,11
Musculo-skeletal (Superficial)	P	P	P	İ	P	2	P	P	P			4,5,6,7,11
Intravascular	1	<u> </u>	1	Ì	Ì			İ				
Other (Specify)												
Cardiac Adult	1		İ	İ								
Cardiac Pediatric	1			<u> </u>				İ				
Intravascular (Cardiac)	1											
Trans-esoph. (Cardiac)												1
Intra-cardiac	1			T				1				
Other (Specify)	†											T
Peripheral vessel	N	N	N		N	2	N	N	N			4,5,6,7,11
Other (Specify)	1	Ì	<u> </u>								i	ĺ

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

Prescription Use Only (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K/23992 Sean M. Boyd -S

System: Aplio 500 V3.0 Transducer: PLT-1204BX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on '								····
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	†		† 	-		İ		<u> </u>				ļ
Fetal	1											
Abdominal	\top											
Intra-operative (Abdominal)	T											
Intra-operative (Neuro)	T											
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P			5,7
Neonatal Cephalic												
Adult Cephalic											·····	
Trans-rectal	\top											
Trans-vaginal		Ī										
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	P	P	P		,	5,7
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P			5,7
Intravascular	1	T										
Other (Specify)												
Cardiac Adult	T^{-}									T		
Cardiac Pediatric												
Intravascular (Cardiac)		Г										
Trans-esoph. (Cardiac)		Г								T .		
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	P	P		P	2	P	P	P			5,7
Other (Specify)	T]							

 $N=\mbox{new}$ indication; $P=\mbox{previously}$ cleared by FDA; $E=\mbox{added}$ under this appendix Previous 510(k) of the transducer: K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

51000 K12399 > Sean M. Boyd -S

Transducer: PLT-1204MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod		Operati									
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	Ť		1									
Fetal	T											
Abdominal	T	Π										
Intra-operative (Abdominal)	1											
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	1	Ì	Ì				İ					ľ
Small Organ (Specify) (1)	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Neonatal Cephalic	İ			Ì								
Adult Cephalic	\top	Ī										
Trans-rectal				İ				Ì				
Trans-vaginal							İ	Ì	,			Ì
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	P	P		P	2	Р	Р	P		P	5,7,8,9,10
Musculo-skeletal (Superficial)	P	P	P		P	2	P	P	P		P	5,7,8,9,10
Intravascular												
Other (Specify)	1		1									
Cardiac Adult			ĺ				ĺ	İ				
Cardiac Pediatric			1					Ì				
Intravascular (Cardiac)					İ						Ī	i i
Trans-esoph. (Cardiac)												
Intra-cardiac						<u> </u>		1				
Other (Specify)			Ì		1			T				
Peripheral vessel	P	P	P		P	2	P	P	Р		P	5,7,8,9,10
Other (Specify)			1		1			1		T		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K121422

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Prescription Use Only (Per 21 CFR 801.109)

1000 K123992 Sean M. Boyd -S

Transducer: PET-508MA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on							········	
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	+		1				'					
Fetal												
Abdominal .	T											
Intra-operative (Abdominal)	Ţ											
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	T											
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal						ľ						
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)			1									
Intravascular	1		1									
Other (Specify)	1											
Cardiac Adult	1			1								
Cardiac Pediatric												
Intravascular (Cardiac)	T	Π		T								
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4,13
Intra-cardiac												
Other (Specify)	1	Π	T									
Peripheral vessel	1	Π										
Other (Specify)	T	Γ										

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K121422

Note 1	Small organ	includes	thyroid,	breast and	testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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Prescription Use Only (Per 21 CFR 801.109)

Sean M. Boyd -S

Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	В			CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D -	Other [Note]
Ophthalmic	1-											
Fetal									-		ļ	
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)	ŀ										F	
Laparoscopic					·							
Pediatric	T		Ì						*		İ	Ì
Small Organ (Specify) (1)	T		ĺ							ĺ		i
Neonatal Cephalic	İ		Ì									
Adult Cephalic					•							
Trans-rectal			Ì	Ť –						ļ		Ì
Trans-vaginal											<u> </u>	
Trans-urethral				T							İ	
Trans-esoph. (non-Card.)	T										l	T
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	Ī		İ				i					
Intravascular	Ť						Ì				i	†
Other (Specify)				<u> </u>					*****			<u> </u>
Cardiac Adult												
Cardiac Pediatric			T								<u> </u>	
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4,13
Intra-cardiac	1			Ϊ''''						<u> </u>		
Other (Specify)				1								
Peripheral vessel	1		Ì									
Other (Specify)	1		ĺ					İ		i –		<u> </u>

 $N=\mbox{new}$ indication; $P=\mbox{previously}$ cleared by FDA; $E=\mbox{added}$ under this appendix Previous 510(k) of the transducer; K121422

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INDIE 1	l Small organ	micinaes i	HVIOIO.	preast and	restrete

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

(K) C/1379

Sean M. Boyd -S

Transducer: PET-512MC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod		Operati								 .	
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	+			<u> </u>								<u> </u>
Fetal	T											
Abdominal	T											
Intra-operative (Abdominal)												
Intra-operative (Neuro)	T											
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic	T											
Trans-rectal	T		T	ľ								
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)	T	Π				•						
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	T								_			
Intravascular	Ť		<u> </u>							1		
Other (Specify)	1										<u> </u>	1
Cardiac Adult	Ť		ĺ		Ì							
Cardiac Pediatric	1		Ì	T	ĺ			<u> </u>		Ì	Ť T	1
Intravascular (Cardiac)	1				İ							
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4,13
Intra-cardiac	T-	Π	T	T								
Other (Specify)	\top		T									
Peripheral vessel	T	T	T					1			Π	T
Other (Specify)		Γ	1	T				1				Ī

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103629

Moto 1	Crosti organ	, includes th	arenid beans	t and testicle.
INDIE I	เ อเแลน เหษลเ	1 11111.11111125 111	VIUIL IIICAS	a and resulties.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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Transducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	\dagger				•							
Fetal	T		T									
Abdominal	T											
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic	T					-						
Pediatric												
Small Organ (Specify) (1)	T											
Neonatal Cephalic	T		T									
Adult Cephalic	1											
Trans-rectal	T		1									1
Trans-vaginal	T		<u> </u>					1-		1		
Trans-urethral			1									
Trans-esoph. (non-Card.)	T	Γ	İ		<u> </u>							
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	1											
Intravascular	ĺ											
Other (Specify)												
Cardiac Adult	1		T	P								
Cardiac Pediatric	T	Γ	Τ	P			l					
Intravascular (Cardiac)	1											
Trans-esoph. (Cardiac)												
Intra-cardiac	1											
Other (Specify)			T									
Peripheral vessel	T	Γ		P			Ţ.					
Other (Specify)	1		T^-		T							

 $N=\mbox{new}$ indication; $P=\mbox{previously}$ cleared by FDA; $E=\mbox{added}$ under this appendix Previous 510(k) of the transducer: K121422

Note:	l Small organ	i includes thyroid	breast and testicle	

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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510(k)

Sean M. Boyd -S

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Transducer: PC-50M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on	· · · ·	***						
Specific (Tracks 3)	В		PWD		Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	1		1									
Fetal	T								,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
Abdominal	T											
Intra-operative (Abdominal)												
Intra-operative (Neuro)	T									T		
Laparoscopic												
Pediatric			İ							Ì		
Small Organ (Specify) (1)	1		1									
Neonatal Cephalic												
Adult Cephalic	1										i	
Trans-rectal												ĺ
Trans-vaginal	1											
Trans-urethral			İ									
Trans-esoph. (non-Card.)	1	<u> </u>										
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)										1		
Intravascular	1							Ï		1		
Other (Specify)												
Cardiac Adult	1		1	P					-			
Cardiac Pediatric	T			P								
Intravascular (Cardiac)	T											[
Trans-esoph. (Cardiac)	T		T							Γ	i	
Intra-cardiac		<u> </u>	T									
Other (Specify)	1											
Peripheral vessel	T	Γ	T	P	<u> </u>							
Other (Specify)	Ť									T		

 $N=\mbox{new}$ indication; $P=\mbox{previously}$ cleared by FDA; $E=\mbox{added}$ under this appendix Previous 510(k) of the transducer: K121422

	Note	1	Small	organ	includes	thyroid,	breast	and	testicle.
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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Note 14 Boost

(Division Sign Off)

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